



Seroprevalence of Hepatitis C Virus Antibodies among Blood Donors of North India: A Prospective Study

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Abstract

Background: Blood transfusion is an integral and life-saving intervention but simultaneously blood is one of the major sources of transmission of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), syphilis and many other infections. The purpose of the present study was to study the seroprevalence of anti-HCV antibodies in healthy blood donors in a hospital based blood bank in Malwa region of Punjab, North India and to compare with other studies undertaken in other parts of India to assess the epidemiology of this infection in the community.

Methods: Serum samples of 10945 donors were tested for various viral markers including HIV 1 & HIV 2, HBsAg and HCV by 3rd generation ERBA LISA ELISA kits supplied by Transasia Bio-medicals Pvt. Ltd. for the period of one year. **Results:** Out of total 10945 blood donors tested for anti-HCV antibodies, 268 (2.44%) donors were found to be reactive. The seroprevalence of HCV in the blood donors of Malwa region of Punjab was found to be high as compared to the studies from various parts of India. **Conclusion:** High Seroprevalence of anti-HCV antibodies in the donor population reflects the lack of awareness regarding the spread of HCV infection in the general population.

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INTRODUCTION

Blood transfusion is an integral part of management and life-saving intervention in medical fieldbut simultaneously unsafe transfusion practices carry the risk of transmission of the life threatening transfusion transmissible infections (TTIs).^[1] Blood is one of the major sources of transmission of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), syphilis, malaria and many other infections.^[2,3] To ensure safe and adequate blood transfusion services, an integrated strategy has been implemented through India's National blood policy. The main components of this strategy include a collection of blood only from voluntary, non-remunerated blood donors, screening for all TTIs as per the Drug and Cosmetics Rules and reduction of unnecessary transfusion.^[4,5]The prevalence of the transfusion transmitted infections (TTIs), among blood donors allows for assessment of epidemiology of these infections in the community.^[6]

Hepatitis C virus (HCV) infection is a major public health problem occurring in about 180 million people worldwide. Three to four million people are newly infected each year.^[7] According to the Indian National Association for the Study of the Liver, nearly 12.5 million Indians are suffering from the Hepatitis C disease, with death rate exceeding over one lakh.^[8]HCV is known for its chronicity and leads to cirrhosis in about 10 to 20 per cent of

patients and may further progress to hepatocellular carcinoma (HCC).^[5]

Blood transfusion is the most common mode of transmission of HCV as it allows a large quantum of infective virions into the recipient. The global seroprevalence of HCV among blood donors varies from 0.4 to 19.2 per centand the estimated risk for HCV transmission is from 0.10 to 2.33 per million units transfused.Other modes of transmission include perinatal spread and high risk sexual behaviour.^[5] In India, mandatory screening for HCV was introduced in 2002.^[9]

To the best of our knowledge, this is the only study from Malwa region of Punjab, North India conducted on the seroprevalence of anti-HCV antibodies among blood donors.

AIMS AND OBJECTIVES:

1. To study the seroprevalence of HCV in voluntary and replacement blood donors.
2. To compare with other studies undertaken in other parts of India to assess the epidemiology of this infection in the community.

MATERIAL AND METHODS

This prospective study was undertaken in the Department of Immuno-haematology and Blood Transfusion, at a tertiary care instituteofNorth India for the period of one year. Ethical clearance was taken by the Institutional Ethical Committee. The donors were either voluntary or replacement donors. Informed consent of each donor was taken.

Medical history of each donor was taken, physical examination was done and findings were recorded in the prescribed performa. Consent for infectious marker testing was obtained from all donors at the time of pre-donation counselling. Each blood donor was selected according to Drug and Cosmetic Rules, 1945 (DCR) and its amendment 1992 & identified by a unique donor registration number. All serum samples obtained at the time of whole blood donation were tested for HBsAg, HCV, HIV, syphilis and malaria as part of routine testing.

Serum samples of 10945 donors were tested for various viral markers including HIV 1 & HIV 2, HBsAg and HCV by 3rd generation ERBA LISA ELISA kits supplied by Transasia Bio-medicals Pvt. Ltd. The exact procedure and manufacturers' instruction on ELISA kits were followed. The data collected was entered into a Microsoft Office Excel 2007 sheet and percentage and proportions for each variable were calculated. $P < 0.05$ was set as the level of significance.

RESULTS

A total of 10,945 donors were screened and among these, 65.86% (7208) were voluntary and 34.14% (3737) were replacement blood donors (**Figure 1**).

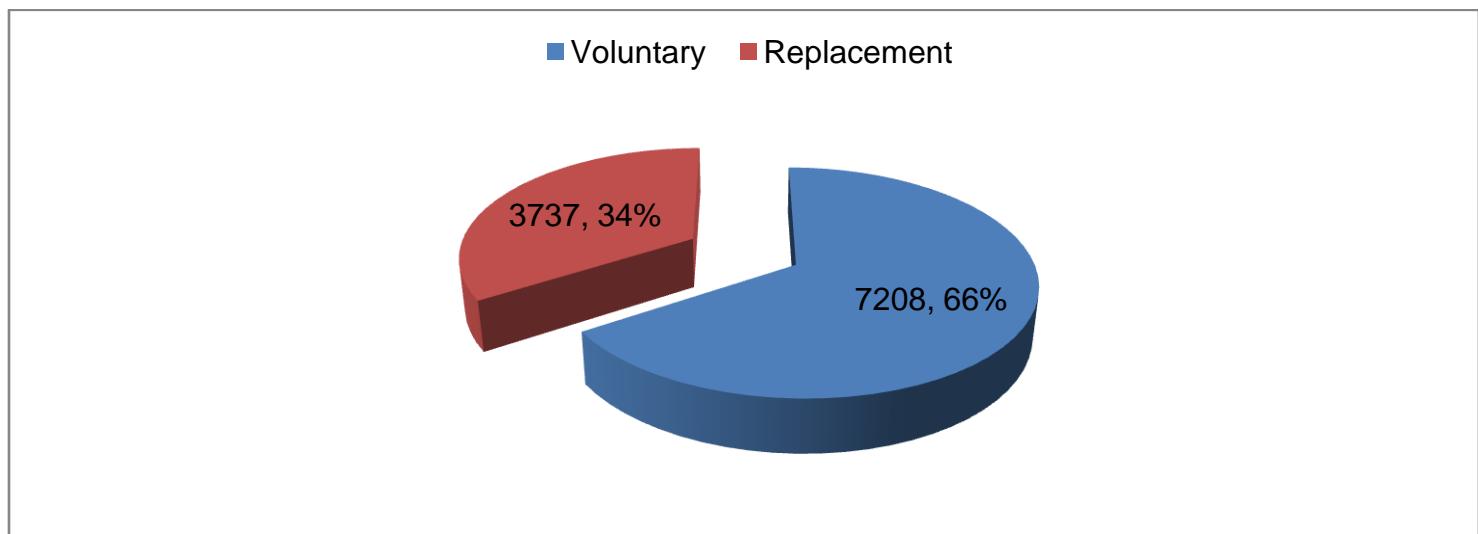


Figure 1: Distribution of blood donors according to type of donor

Table 1 show that donors in the age group of 18-30 years contributed maximally involuntary as well as replacement donors group. Donors in the age group 31-50 years formed the second

largest group. Thereafter the contribution towards blood donation decreased with increase in age and donors beyond 51 years contributed just 1.9%.

Table 1: Distribution of blood donors according to the age of donor

Age Group (yrs)	VOLUNTARY		REPLACEMENT	
	No. of Donors	Percentage	No. of Donors	Percentage
18-30	4814	66.8	2045	54.8
31-50	2254	31.3	1620	43.3
51-65	140	1.9	72	1.9
TOTAL	7208	100	3737	100

Of the 10,945 donors, the majority of blood donors in both replacement and voluntary groups were males comprising 99.6%(3722) and 97.4%(7023) respectively. While there were only (0.4%) 15 females out of 3737 replacement donors, there was much more participation in the voluntary group by females i.e. 185 (2.6%) females out of 7208 voluntary donors.

Out of total 10945 blood donors tested, 268 (2.44%) donors were found to be reactive for anti-HCV antibodies. Majority of the HCV seropositive donors were from replacement group i.e. 3.45% while in voluntary donors group, HCV seropositivity rate was 1.92%. The HCV seropositivity difference between voluntary and replacement donors was found to be highly significant statistically ($p<0.001$); (Table 2).



Table 2: HCV seroprevalence in replacement versus voluntary blood donors

Type of Donor	Anti HCV reactive blood donors	Percentage
Voluntary (7208)	139	1.92
Replacement (3737)	129	3.45
Total [10945]	268	2.44

$\chi^2 = 23.916$; df = 1; p < 0.001; Highly Significant

There was no HCV reactive female blood donor in both voluntary as well as replacement groups. All HCV reactive donors were males.

Table 3 shows that in voluntary donors, maximum HCV seropositivity was seen in 31-50 years age group i.e. 2.61% (59/2254) followed by 1.62% (78/4814) in 18-30 years age group. The lowest HCV seropositivity(1.42%) was seen in 51-65 years age group. This age specific difference was statistically significant (p=0.016)

In replacement donors, maximum HCV seropositivity was present in 18-30 years age group i.e. 3.91% (80/2045) followed by 31-50 years age group i.e. 3.02% (49/1620) cases. But the difference was not significant statistically (p=0.093). There was no HCV seropositive donor in 51-65 years age group.

All serum samples were also tested for HBsAg and HIV antibodies as part of routine testing by ELISA. Seroprevalence for HBsAg and HIV was found to be 0.95% and 0.12% respectively.

Table 3: HCV seropositivity according to age distribution among blood donors

Age Group (yrs)	Voluntary			Replacement		
	Total Donors	Anti HCV reactive blood donors	%age	Total Donors	Anti HCV reactive blood donors	%age
18-30	4814	78	1.62	2045	80	3.91

31-50	2254	59	2.61	1620	49	3.02
51-65	140	2	1.42	72	0	0
TOTAL	7208	139	1.92	3737	129	3.45
$\chi^2 = 8.262; df = 2; p = 0.016;$ Significant				$\chi^2 = 4.760; df = 2; p = 0.093;$ Not Significant		

DISCUSSION

Blood transfusion service (BTS) is an integral and indispensable part of the healthcare system. The main objective of BTS is to ensure safety, adequacy, accessibility and efficiency of blood supply at all levels.^[10] With every unit of blood, there is 1% chance of transfusion associated problems including TTI.^[11] The risk of TTI has declined dramatically in high income nations over the past two decades.^[12] But the same may not hold good for the developing countries. The national policy for blood transfusion services in our country is of recent origin and the transfusion services are hospital based and fragmented.^[13] To prevent TTIs as a delayed complication of blood transfusion, Government of India mandates the screening of each and every unit of blood as per drugs and cosmetic rules. Despite following all measures such as strict donor selection criteria, voluntary, non-remunerated donation, and more sensitive methods to detect TTIs, some transmission events are still possible because of the window period, false negative results, and other technical errors.^[4]

The present study included 10945 healthy blood donors, of which 7208 (65.86%) were voluntary and 3737 (34.14%) were replacement (**Figure1**). This is in concordance with many other studies which showed that voluntary

donors constitute a single largest group. In a retrospective study conducted by Patel and associates at Western Ahmedabad, 95.56% donors were voluntary.^[14] Similarly there were 64.78% voluntary donors in the study of Pallavi P et al.^[15] However a predominance of replacement donors was noted by Singh et al. (82.4%)^[16], Kakkar et al. (94.7%)^[17], Singh et al. (84.43)^[18], Pahuja et al. (99.48%)^[19] and Arora et al. (68.6%)^[11] from other regions of the country. Voluntary donors (VD) are motivated blood donors who donate blood at regular intervals and their majority in our study reflects high level of awareness regarding the blood transfusion among general population of Malwa region of Punjab.

Better response towards blood donation in the present study was seen in the younger age group i.e. 18-30 years (**Table 1**) which is similar to that observed in the study done by Thakral et al.^[20] Also in study by Malik et al. most of the donors belonged to age group of 18-35 years (78.3%).^[21] Donors in the age group 31-50 years formed the second largest group in present study. Thereafter, the contribution towards blood donation decreased with increase in age in both voluntary as well as replacement donors; the donors beyond 50 years contributed the least. This might be due to the fact that large numbers of elderly age

group donors are deferred due to their age related health issues.

Though there was some participation by females in blood donation, the majority of blood donors in our study were males comprising 97.4% and 99.6% in voluntary and replacement groups respectively. There were only 200 female donors, out of which 15 (0.4%) females were in replacement group and 185 (2.6%) were in voluntary group which is comparable to the studies of Rao and Annapurna et al. from Pune^[22], Rose et al. from Vellore^[23]. In present study, lesser number of female donors as compared to their male counterparts may be due to the fact that Indian females are usually anemic and unfit to donate blood. Cultural factors, family constraints and fear of donating blood due to lack of proper education may be other reasons for their lower turnout.

In our study the seroprevalence of HCV was found to be 2.4% (**Table 2**). There was no HCV reactive female blood donor in both voluntary and replacement groups. All HCV reactive donors were males. This difference may be due to lesser number of female donors in present study. Similarly in another retrospective study to assess the frequency distribution, including demographic and geographical data of patients with Hepatitis C in different regions of Punjab, Hepatitis C infection was found to be more than twice prevalent in males as compared to females. This may be explained from the fact that males are more prone to harbour the risk factors for this infection like drug abuse and unprotected sex.^[24]

Majority of the HCV infected donors were from replacement group i.e. 3.45% and

voluntary donors contributed only 1.92%. *The difference of HCV seroprevalence between these two groups was found to be highly significant statistically ($p<0.001$).* This difference may be due to the fact that many times replacement donors are forced to donate blood under some kind of pressure or hidden paid donors who donate blood as replacement after hiding their ill health and high risk behavior. Our study corroborates the study by Pahuja et al., who reported the HCV seroprevalence of 2.23% from Delhi.^[17] However Garg et al reported an HCV seroprevalence of 0.28% in blood donors of Western India.^[26] Internationally, various studies have reported an HCV prevalence range of 0.42-1.2%.^[17]

The seroprevalence of HCV in the blood donors of Malwa region of Punjab was found to be high as compared to the studies from various parts of India (**Table 4**). This is really worrisome as it reflects the lack of awareness regarding the spread of HCV infection in the general population. It has also been observed that seroprevalence of HCV is highest of all TTIs i.e. HCV, HIV and HBsAg in the population under study as shown in the results. However in other states of North India, maximum seropositivity rate is of HBsAg followed by HCV and HIV (**Table 4**).

The present study (**Table 3**) shows that in voluntary donors, maximum HCV seropositivity was seen in 31-50 years age group (2.61%) followed by 18-30 years (1.62%) and lowest (1.42%) in 51-65 years of age group. *This difference was found to be statistically significant ($p=0.016$).* This is in agreement with study done among HCV patients by Singh P et al., in which the prevalence of HCV infection was highest in age group of 41-60 years

followed by 21-40 years.^[24] This may be due to the long asymptomatic period of Hepatitis C infection with symptoms appearing after a long latent period. Moreover, the above age groups are most likely to indulge in risky behavior and practices such as unprotected sex and substance abuse. However in

replacement donors, maximum HCV seropositivity was present in 18-30 years age group (3.91%) followed by 31-50 years age group (3.02%). However this difference was not found to be significant ($p=0.093$).

Table IV: Comparison of TTI prevalence rate in different parts of India

Author & Year	Place	HIV	HBsAg	HCV
Gupta et al ^[27] (2001-2003)	Ludhiana	0.08%	0.66%	1.09%
Pahuja et al ^[17] (2002-2005)	Dehli	0.56%	2.23%	0.66%
Bhattacharya et al ^[6] (2004-2005)	West Bengal	0.28%	1.46%	0.31%
Chandra et al ^[28] 2001-2006	Lucknow, UP.	0.23%	1.96%	0.34%
Arora et al ^[9] (2002-2006)	South Haryana	0.3%	1.7%	1.0%
Pallavi et al ^[13] (2004-2008)	Mysore	0.44%	1.27%	0.23%
Sawke et al ^[29] (2006-2008)	Bhanpur, MP.	0.51%	2.90%	0.57%
Bhawani et al ^[30] (2004-2009)	Vikarabad, AP	0.39%	1.41%	0.84%
Jasani et al ^[31] (2004-2011)	Piparia, Gujarat.	0.25%	1.35%	0.85%

Dayal et al ^[32] (2006-2011)	Etawah, UP.	0.19%	2.63%	0.34%
Patel et al ^[14] (2005-2011)	Sola, Ahmedabad, Gujarat.	0.08%	0.30%	0.09%
Present Study	Faridkot, Punjab.	0.12%	0.95%	2.44%

It can thus be concluded that HCV seroprevalence in healthy blood donors of Malwa region of Punjab is the highest (2.44%) followed by HBsAg (0.95%) and HIV (0.12%) seroprevalence. Also seroprevalence is more in the replacement donors which represents a large reservoir of infection capable of inflicting significant disease burden on the society. As the TTI seropositivity was lower in the voluntary blood donors, there should be concerted efforts to encourage voluntary blood donation. Voluntary blood donors are the cornerstone of a safe and adequate supply of blood.

In a recent questionnaire based study it was concluded that, in-spite of having awareness about parenteral route of transmission of HCV infection, a substantial proportion of family physicians in the Punjab state persist to reuse needles and syringes. Knowledge about the virology, clinical symptoms, diagnostic tests and management approaches are poor among a considerable section of family physicians in Punjab.^[25]

With the advent of nucleic acid amplification techniques (NAT), western countries have

decreased the risk of transfusion transmitted infections (TTI) to a major extent. But its high financial cost is of concern, especially in economically restricted countries like ours. Along with advanced technology such as NAT for donor screening, other factors such as public awareness, vigilance of errors, educational and motivational programs may help in decreasing the infection.

CONCLUSION

To conclude our study shows that there should be concerted efforts to encourage voluntary blood donation. Voluntary blood donors are the cornerstone of the safe and adequate supply of blood. Donor population serosurveys, can address the gaps and inform policy makers in efforts to alleviate the public health burden of HCV infection across afflicted regions worldwide. High HCV seroprevalence in healthy blood donors of Malwa region of Punjab in our study reflects the lack of awareness regarding the spread of HCV infection in the general population. Therefore, public awareness programs, and institution of sufficient public health measures must be implemented without delay. Transmission of

TTIs during the window period is also a threat to blood safety. So adding nucleic acid amplification testing (NAT) for HCV, HIV and HBsAg to mandatory routine blood screening protocol will definitely help in controlling the transmission of infection. Hence with the

implementation of strict donor selection criteria, use of sensitive screening tests like NAT and establishment of strict guidelines for rational use of blood transfusion, it may be possible to reduce the incidence of TTIs in Indian scenario.

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